510(k) Summary

OCT 1 2012

SOLSTICE OCT System

Submitted By:

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510(k) Contact:

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Date Prepared: March 13th, 2012

Trade Name: Solstice OCT System

Classification: KWP, 21 CFR 888.3050, Class II, Spinal Interlaminal Fixation Orthosis.

Predicate Devices: The Sentinel Spinal System (K093043), Theken Atoll System (K083073), Biomet Altius System (K113593), Blackstone Ascent System (K073654)

Device Description:

The SOLSTICE OCT System is a temporary, titanium alloy (6AL-4V-ELI per ASTM F 136), multiple component system comprised of a variety of non-sterile, single use implantable components. When assembled, the components create a rigid structure providing stabilization and promote spinal fusion. The system consists of an assortment of occipital plates, occipital bone screws, polyaxial screws, hooks, rods, cross connectors and locking breakaways.

Intended Use of the Device:

When intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (Occiput – T3), the SOLSTICE OCT System, when properly used, is intended for: Degenerative Disc Disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; spinal stenosis; fracture/dislocation; Atlanto/axial fracture with instability; occipitocervical dislocation; revision of previous cervical spine surgery; and tumors.

When used with the occipital plate, the bone screws are limited to occipital fixation only. The bone screws are not intended to be used in the cervical spine.

The use of polyaxial screws is limited to placement in T1-T3 in treating thoracic conditions only. They are not intended to be placed in the cervical spine.

The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

Technological Characteristics:
The Solstice OCT System is substantially equivalent to the predicate system in terms of design, materials, and indications for use.

Material:

The SOLSTICE OCT System is manufactured from medical grade titanium alloy described by ASTM F136 (Ti 6Al-4V-ELI) implant grade titanium alloy.

Performance Data:
Dynamic testing in accordance with ASTM F1717 was presented to demonstrate the substantial equivalency of the SOLSTICE OCT System.

Conclusion:

The indication/intended use of the modified device as described in its labeling has not changed. Furthermore, the fundamental scientific technology of the modified device has not changed. The SOLSTICE OCT System was shown to be substantially equivalent to the previously cleared devices in indications for use, design, function, and materials used.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 1 2012

Life Spine
% Mr. Randy Lewis
Regulatory Affairs, Quality Assurance Manager
2401 West Hassell Road, Suite 1535
Hoffman Estates, Illinois 60169

Re: K120998
Trade/Device Name: Solstice OCT System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: II
Product Code: KWP
Dated: August 29, 2012
Received: September 04, 2012

Dear Mr. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) number (if known): K120998

Device Name: Solstice OCT System

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Prescription Use _x_ (Part 21 CFR 801 Subpart D) And/Or Over-the-Counter Use ____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120998